

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS, INC.,)	
)	
Plaintiff,)	C.A. No. 12-367 (GMS)
)	(CONSOLIDATED)
v.)	
)	REDACTED -
HOSPIRA, INC.,)	PUBLIC VERSION
)	
Defendant.)	

PROPOSED FINAL PRETRIAL ORDER

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FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS, INC.,)	
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Plaintiff,)	C.A. No. 12-367 (GMS)
)	(CONSOLIDATED)
v.)	
)	CONFIDENTIAL – FILED UNDER
HOSPIRA, INC.,)	SEAL
)	
Defendant.)	

PROPOSED FINAL PRETRIAL ORDER

This matter having come before the Court at a pretrial conference held pursuant to Fed. R. Civ. P. 16, Jack B. Blumenfeld and Maryellen Noreika, Morris, Nichols, Arsht & Tunnell LLP, 1201 North Market Street, Wilmington, Delaware 19899, (302) 658-9200, and William F. Lee, Lisa J. Pirozzolo, Robert Galvin, and Sean Thompson, Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109, (617) 526-6000, having appeared as counsel for Plaintiff Cubist Pharmaceuticals, Inc. (“Cubist” or “Plaintiff”) and John C. Phillips, Jr. and Megan C. Haney, Phillips, Goldman & Spence, P.A., 1200 North Broom Street, Wilmington, DE 19806, (302) 655-4200 and James F. Hurst, Gail J. Standish, Peter E. Perkowski and David P. Dalke, Winston & Strawn LLP, 35 W. Wacker Drive, Chicago, Illinois 60601, (312) 558-5600 and 333 S. Grand Avenue, Los Angeles, California 90071, (213) 615-1700, having appeared as counsel for defendant Hospira, Inc. (“Hospira” or “Defendant”), the following actions were taken:

I. JURISDICTION

This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. Jurisdiction is invoked under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Jurisdiction is not disputed.

II. STIPULATION AND STATEMENT

The following stipulations and statements were submitted and are attached to and made a part of this Order:

A. Statement of Uncontested Facts

1. The parties' statement of uncontested facts is set forth in **Exhibit 1**.
2. These uncontested facts require no proof at trial and are part of the evidentiary record in the case.

B. Statement of Contested Issues of Fact and Law

1. Cubist's statement of contested issues of fact and law is attached as **Exhibit 2**.
2. Hospira's statement of contested issues of fact and law is attached as **Exhibit 3**.
3. If the Court determines that any issue identified in a party's Statement of Contested Issues of Fact and Law as an issue of fact is more properly considered an issue of law, it shall be so considered. Similarly, if the Court determines that any issue identified in a party's Statement of Contested Issues of Fact and Law as an issue of law is more properly considered an issue of fact, it shall be so considered.

C. Exhibit Lists

1. Cubist's list of exhibits and Hospira's objections to Cubist's list of exhibits are attached as **Exhibit 4**.
2. Hospira's list of exhibits and Cubist's objections to Hospira's list of exhibits are attached as **Exhibit 5**.
3. Subject to the remaining provisions of this Order, no party may use an exhibit not present on its exhibit list absent good cause shown. Each party may use exhibits from the

other party's trial exhibit list, even if not separately listed on its own exhibit list. Any exhibit, once admitted at trial, may be used equally by each party for any proper purpose in accordance with the Federal Rules of Evidence. The listing of a document on a party's list is not an admission that such document is relevant or admissible when offered by the opposing party for the purpose that the opposing party wishes to admit the document.

4. Each party may offer exhibits not set forth in its exhibit list for purposes of impeachment.

5. The parties agree that the demonstrative exhibits the parties intend to use at trial do not need to be included on their respective lists of trial exhibits. Plaintiff's demonstratives will be identified with PDX numbers. Defendant's demonstratives will be identified with DDX numbers.

6. The parties will identify the witnesses expected to testify by 6:00 p.m. two days before the direct examination is to take place. Each party will give notice at 8:00 p.m. two days before when it intends to complete the presentation of its evidence in its case in chief.

7. The parties have agreed to the following procedure for the exchange of trial exhibits to be used with witnesses. The parties shall identify for each witness the trial exhibits that they expect to use in an examination by 7:00 p.m. on the day before the examination is expected to take place. Objections to trial exhibits shall be made by 8:30 p.m. the day before the examination is expected to take place. The parties shall then meet and confer in an attempt to resolve any objections to the trial exhibits that are expected to be used during examinations.

8. The parties have agreed to the following procedure for the exchange of demonstrative exhibits to be used with witnesses on direct examination. For the direct examination of each witness, the calling party shall provide the other party with final copies

(subject only to addressing evidentiary objections and rulings) of all demonstrative exhibits to be used in the direct examination of that witness by 7:00 p.m. the day prior to the witness for whom the demonstrative is relevant will testify in Court. With regard to the exchange of demonstrative exhibits, the calling party must provide color PDF files or color copies (on 8½” x 11” paper or larger) of all demonstrative exhibits to be used with each witness on direct examination. The notice provisions of this paragraph shall not apply to demonstrative exhibits created in the courtroom during testimony at trial or the enlargement, simple highlighting, ballooning, or excerpction of trial exhibits or testimony. The party cross-examining the witness shall notify the calling party of any objections that it has to the demonstrative exhibits by 8:30 p.m. the day prior to the witness testifying. The parties shall then meet and confer regarding any objections to any demonstrative exhibit.

9. The parties shall identify any trial exhibits and identify and serve copies of any demonstrative exhibits as color PDF files or color copies (on 8½” x 11” paper or larger) to be used in opening arguments by 9:00 p.m. on the day before trial is to commence. The parties shall make objections, if any, to the exhibits or demonstratives disclosed by 8:00 a.m. the following morning.

10. Any objections to any trial exhibit or demonstrative exhibit that is maintained following the meet and confer process may be taken up with the Court prior to the opening or the witness’s testimony or as otherwise directed by the Court.

11. Any exhibit identified on a party’s exhibit list and not objected to is deemed to be admissible and may be entered into evidence by the party, except that nothing herein shall be construed as a stipulation or admission that the document is entitled to any weight in deciding the merits of this case.

12. The parties stipulate to the authenticity of all exhibits, except where specifically indicated with specific reasons for the objection noted. Any objection to a document's authenticity must be made in this Pretrial Order.

13. Legible copies of United States patents and the contents of the Patent and Trademark Office file histories may be offered and received in evidence in lieu of certified copies thereof, subject to all other objections that might be made to the admissibility of certified copies.

D. The Parties' List of Witnesses to be Called at Trial

1. Cubist's list of the names and addresses of the fact and expert witnesses that it intends to call at trial, together with Hospira's objections thereto, is attached as **Exhibit 6**.

2. Hospira's list of the names and addresses of the fact and expert witnesses that it intends to call at trial, together with Cubist's objections thereto, is attached as **Exhibit 7**.

3. Each side's list of deposition designations is incorporated by reference into its list of witnesses that it intends to call at trial, except that a party may not call a witness for live testimony if that witness appears only on the list of deposition designations and not on the list of witnesses.

4. Any witness not listed in the exhibits referenced above will be precluded from testifying absent good cause shown, except that each party reserves the right to call such rebuttal witnesses (who are not presently identifiable) as may be necessary, on reasonable notice to the opposing party.

5. The parties' lists of witnesses shall indicate (1) which witnesses will be called in the absence of reasonable notice of opposing counsel to the contrary and (2) which witnesses may be called as a possibility only.

6. Cubist and Hospira have agreed to exchange a list identifying the specific witnesses that each party intends to call in its case-in-chief by 12:00 p.m. on Sunday, February 16, in the order that it intends to call those witnesses at trial. Further, each party shall identify whether each witness will be called live or by deposition.

E. Qualification of Expert Witnesses

1. Cubist's statement setting forth the qualifications of each of Cubist's expert witnesses, Hospira's objections thereto, and the subject matter of each expert witness's testimony is attached as **Exhibit 8**.

2. Hospira's statement setting forth the qualifications of each of Hospira's expert witnesses, Cubist's objections thereto, and the subject matter of each expert witness's testimony is attached as **Exhibit 9**.

1. A chart of Cubist's deposition designations, Hospira's objections to Cubist's deposition designations, Hospira's counter-designations, and Cubist's objections to Hospira's counter-designations is attached as **Exhibit 10**.

2. A chart of Hospira's deposition designations, Cubist's objections to Hospira's deposition designations, Cubist's counter-designations, and Hospira's objections to Cubist's counter-designations is attached as **Exhibit 11**.

3. To the extent admissible, a party may introduce deposition testimony by videotape or by transcript. When deposition designation excerpts are introduced, all admissible deposition counter-designation excerpts, whether offered by videotape or by transcript, will be introduced simultaneously in the sequence in which the testimony was originally given. To the extent such designations are read or played in open court, each party will be charged for the time

taken to read or play its designations, as measured by the proportion of lines of testimony for its designations to the total number of lines of testimony read or played. A party who wishes to enter deposition testimony into the record shall provide to the other party at least 24 hours' notice of the name of the witness and the specific excerpts that the party intends to enter into the record. The parties shall meet and confer regarding any objections to deposition testimony sought to be introduced into the record at trial.

4. Any deposition testimony not specifically identified on a party's deposition designation list still may be used at trial for the purpose of impeachment, if otherwise competent for such purposes.

G. Special Damages

This case does not involve any claims for special damages.

H. Waivers of Claims and Defenses

The parties have agreed to the following stipulation regarding infringement of the patents-in-suit:

1. Hospira filed Abbreviated New Drug Application No. 202857 ("ANDA No. 202857"), under 21 U.S.C. § 355(j)(1) and (2)(A), and New Drug Application No. 23797 ("NDA No. 23797"), under 21 U.S.C. § 355(b)(2), with the United States Food and Drug Administration seeking approval for the commercial manufacture, use, and sale of generic versions of CUBICIN® ("Hospira's Daptomycin ANDA and 505(b)(2) Products").

2. For the purposes of this litigation only, without prejudice to Hospira's arguments that the asserted claims of the patents-in-suit are invalid, expressly reserving Hospira's arguments concerning the proper construction of "daptomycin" and "Formula 3 compound," and

expressly reserving both parties' rights to amend their claims and defenses in the event of any revision to the Court's construction of "daptomycin" and "Formula 3 compound":

- a. The marketing or sale in the United States of Hospira's Daptomycin ANDA and 505(b)(2) Products with their proposed labeling would actively induce infringement of claims 5, 16-17, 34-35, and 42-45 of the '967 patent, unless such claims are found to be invalid or the Court's construction of "daptomycin" is reversed.
- b. The marketing or sale in the United States of Hospira's Daptomycin ANDA and 505(b)(2) Products with their proposed labeling would actively induce infringement of claims 48-52 of the '689 patent, unless such claims are found to be invalid or the Court's construction of "daptomycin" is reversed.
- c. Making, using, offering to sell, selling, or importing Hospira's Daptomycin ANDA and 505(b)(2) Products in/into the United States would directly infringe claims 18, 19, 26, and 28 of the RE'071 patent, unless such claims are found to be invalid, the Certificate of Correction is found to be invalid, or the Court's construction of "Formula 3 compound" is reversed.
- d. Making, using, offering to sell, selling, or importing Hospira's Daptomycin ANDA and 505(b)(2) Products in/into the United States would directly infringe claims 50, 91, 98, 103, 168, 172, 174, 185, and 187 of the '238 patent, unless such claims are found to be invalid or the Court's construction of "daptomycin" is reversed. Should Hospira change its products, specifications,

or written internal specifications such that Hospira contends that its Daptomycin ANDA and 505(b)(2) Products no longer meet at least one of the limitations of the claims listed in the preceding sentence, Hospira will promptly notify Cubist of the change and provide documents and samples sufficient to show the alleged change. In the event of such notification, the parties expressly reserve their rights to seek appropriate relief from the Court.

e. Making, using, offering to sell, selling, or importing Hospira's Daptomycin ANDA and 505(b)(2) Products in/into the United States would directly infringe claims 14, 23, 32, 42, and 53 of the '342 patent, unless such claims are found to be invalid or the Court's construction of "daptomycin" is reversed. Should Hospira change its products, specifications, or written internal specifications such that Hospira contends that its Daptomycin ANDA and 505(b)(2) Products no longer meet at least one of the limitations of the claims listed in the preceding sentence, Hospira will promptly notify Cubist of the change and provide documents and samples sufficient to show the alleged change. In the event of such notification, the parties expressly reserve their rights to seek appropriate relief from the Court.

3. Cubist will not seek to assert patent claims other than those listed above in this litigation, except in the event that Hospira provides notification of a change to its products, specifications, or written internal specifications pursuant to paragraphs 2.d or 2.e above, in which case Cubist shall be entitled to assert additional claims of the '238 and '342 patents.

4. As to ANDA No. 202857 and NDA No. 203797, Hospira will not assert that patent claims other than those listed above (or subsequently asserted pursuant to paragraph 3 above) are invalid or unenforceable.

I. Proposed Findings of Fact and Conclusions of Law

1. Cubist's Proposed Findings of Facts and Conclusions of Law are attached in duplicate as **Exhibit 12**.

2. Hospira's Proposed Findings of Fact and Conclusions of Law are attached in duplicate as **Exhibit 13**.

J. Settlement Negotiations

[REDACTED]

K. Discovery

Discovery in this action is complete.

L. Motions in Limine

1. No motions *in limine* shall be filed; instead, the parties will be prepared to address their evidentiary issues at the Pretrial Conference or during trial (before and after the trial day).

2. Evidentiary issues Cubist intends to raise at the Pretrial Conference are attached in duplicate as **Exhibit 14**.

3. Evidentiary issues Hospira intends to raise at the Pretrial Conference are attached in duplicate as **Exhibit 15**.

III. TRIAL SCHEDULE

1. Trial of this case is expected to take 5 days. Trial is scheduled to begin at 9:00 a.m. on February 18, 2014. Cubist requests that trial instead begin at 9:00 a.m. on February 19, 2014, to accommodate the schedule of one of Cubist's expert witnesses. Hospira opposes this request.

IV. TYPE OF TRIAL

This is a non-jury trial.

V. NUMBER OF JURORS

This is a non-jury trial.

VI. ORDER TO CONTROL COURSE OF ACTION

This Order will control the course of the trial and may not be amended except by consent of the parties and the Court, or by order of the Court to prevent manifest injustice.

SO ORDERED this _____ day of _____, 2014

CHIEF, UNITED STATES DISTRICT JUDGE

MORRIS, NICHOLAS, ARSHT & TUNNELL LLP

PHILLIPS, GOLDMAN & SPENCE, P.A.

/s/ Maryellen Noreika

/s/ Megan C. Haney

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